

REMARKS

Assignee and the undersigned attorney thank Examiner Shaffer for his review of this patent application. Claims 6-15, 22, 26, and 27 have been withdrawn pursuant to an election of species requirement. Claims 1, 3-5, 16, 18-20, 25, 28-31, 33, 34, and 36 are amended above, claims 35 and 37-40 are cancelled, and new claim 41 is added. No new matter has been added by the claim amendments. Assignee respectfully requests reconsideration of claims 1-3, 5, 16-19, 21, 23-25, 28-34, and 36 and consideration of new claim 41. An RCE is being filed concurrently herewith.

Amendments to the Specification

The specification is amended throughout to replace “radial” with “circumferential.” The word “radial” does not accurately describe the grooves shown in Figs. 17, 20, and 21 as such grooves extend around the outer perimeter or circumference of a shaft. Accordingly, Assignee has amended the portions of the specification describing such grooves to use the more appropriate adjective “circumferential.” This amendment is supported by at least the drawings, and no new matter has been added.

Claim Rejections

In the Action, the Examiner rejected claims 1-3, 5, 16-19, 21, 23, and 30-40 under 35 U.S.C. § 102(b) as being anticipated by PCT Publication No. WO 00/40163 to *Faccioli et al.* (“*Faccioli*”). The Examiner rejected claims 24, 25, 28, and 29 under 35 U.S.C. § 103(a) as being unpatentable over *Faccioli* in view of U.S. Patent No. 5,160,335 to *Wagenknecht* (“*Wagenknecht*”). Finally, the Examiner rejected claims 4 and 20 under 35 U.S.C. § 103(a)

as being unpatentable over *Faccioli* in view of U.S. Patent No. 5,405,347 to *Lee et al.* (“*Lee*”).

Claims 1-5, 16, 17, 34, 36, and 41

Amended claim 1 recites:

An external fixation apparatus comprising:
a first member attachable to a first bone segment through a pin;
a lockable ball joint connected to the first member;
a pivot arm attachable to the first member through the lockable ball joint, the pivot arm comprising a first end portion and a second end portion, wherein the first end portion and the second end portion may be translated transversely relative to one another and to a longitudinal axis of the pivot arm; and
a pin clamp coupled to and rotatable about the second end portion of the pivot arm through a lockable joint, the pin clamp being attachable to a second bone segment.

The Examiner asserts that *Faccioli* teaches each and every element of claim 1. However, *Faccioli* fails to teach or suggest each and every element of amended claim 1. More particularly, *Faccioli* does not teach or suggest a pivot arm with first and second end portions that may translate transversely relative to one another.

In the Action, the Examiner refers primarily to Figures 2 and 2B of *Faccioli* and the associated description of these drawings. In *Faccioli*, proximal portion 3 is coupled to central body 2, which is coupled to stem 20, and stem 20 is coupled to first and second jaws 40 and 50 of a clamp. The ends of each of central body 2 are fixed relative to one another, as are the ends of stem 20.

In contrast, amended claim 1 recites a pivot arm coupled to a first member and a pin clamp, each coupling by a lockable joint, and where the pivot arm has first and second end portions that translate transversely relative to one another. One example of this is shown in

Fig. 3 and described at pages 11-12 of the application. More specifically, end 118 moves “either medially or laterally relative to both the longitudinal axis of second member 110 and end 116, depending on the direction in which worm gear 132A is turned [and turning worm gear 132B moves] end 116 either posterior or anterior relative to the longitudinal axis of second member 110 and end 118” See page 12, lines 5-11. In *Faccioli*, neither central body 2 nor stem 20 are a pivot arm with first and second end portions that can be translated relative to one another, as recited in amended claim 1.

For the above reasons, the Examiner should withdraw the rejection of claim 1 as anticipated by *Faccioli*, and claim 1 should be allowed. Inasmuch as claims 2-5, 16, 17, 34, 36, and 41 depend from and thereby include the limitations of claim 1, claims 2-5, 16, 17, 34, 36, and 41 should also be allowed for at least such dependencies.

Claims 18, 19, 21, 23, and 24

Amended claim 18 recites:

An external fixation apparatus comprising:
a first member attachable to a first bone segment through a pin;
a lockable ball joint connected to the first member;
a second member attachable to the first member through the lockable ball joint, the second member comprising a first end portion and a second end portion, the second end portion comprising a shaft extending transversely therefrom with at least one groove extending around at least a portion of a circumference of the shaft; and
a pin clamp attachable to a second bone segment and releasably coupled to and rotatable about the second member, the pin clamp comprising:
a first jaw and a second jaw, the first jaw including a hole that receives the shaft;
a locator pin that is received within the at least one groove of the shaft to releasably couple the second member and the pin clamp;
and

a first bolt that passes through openings in the first and second jaws such that tightening of the first bolt interferes with the shaft and locks rotation of the pin clamp about the second member.

The Examiner asserts that *Faccioli* teaches each and every element of claim 18, but *Faccioli* does not teach or suggest (a) “the second end portion [of the second member] comprising a shaft extending transversely therefrom with at least one groove extending around at least a portion of a circumference of the shaft,” (b) a pin clamp “releasably coupled to” a second member, or (c) “a locator pin that is received within the at least one groove of the shaft to releasably couple the second member and the pin clamp.”

The Examiner asserts that pivot 35 of *Faccioli* teaches the recited shaft of claim 18. However, pivot 35 does not extend transversely from stem 20, but rather pivot 35 is captured within the two prongs 23, 24 of stem 20. The Examiner also asserts that pivot 35 of *Faccioli* includes a hole that extends through the radius of pivot 35 and receives a lock pin 37, and that this teaches the “at least one groove . . .” recited in claim 18. While pivot 35 includes a hole, it does not include a groove “extending around at least a portion of a circumference of the shaft” as recited in amended claim 18.

Additionally, the lockpins 37 of *Faccioli* are for permanently securing pivot 35 between prongs 23, 24 of stem 20, and thus permanently securing the upper jaw 40 of the pin clamp to the stem. (*See Faccioli* at page 9.) In the Action, the Examiner is suggesting that anything coupled is “releasably coupled” simply because it could theoretically be taken apart, but is ignoring that *Faccioli* does not teach or suggest ever removing lockpins 37 from stem 20/pivot 35 once the lockpins secure the pivot between the stem prongs. Moreover, lockpins 37 do not releasably couple “the second member and the pin clamp” as recited in

claim 18 because removing lockpins 37 would merely result in pivot 35 being less secure between the prongs, yet jaws 40 and 50 of the *Faccioli* clamp would still be coupled to pivot 35. In other words, inserting or removing lockpins 37 into the prongs and pivot of the *Faccioli* stem does not releasably couple the stem 20 to the clamp. Accordingly, *Faccioli* does not teach the locator pin limitation of claim 18.

For these reasons, the Examiner should withdraw the rejection of claim 18 as anticipated by *Faccioli*, and claim 18 should be allowed. Inasmuch as claims 19, 21, 23, and 24 depend from and thereby include the limitations of claim 18, claims 19, 21, 23, and 24 should also be allowed for at least such dependencies.

Claims 25, 28, and 29

Amended claim 25 recites:

An external fixation system for attaching pins or wires to at least one bone segment, the system comprising:

a first member;

a second member coupled to the first member, the second member comprising a shaft that extends transversely from an end portion of the second member and has at least one groove extending around at least a portion of a circumference of the shaft; and

a pin clamp comprising:

a first jaw and a second jaw, each of the first and second jaw having openings;

biasing elements received within the openings, the biasing elements adapted to bias the first and second jaws toward each other;

first and second bolts that extend into the openings in the first and second jaws, the first and second bolts adapted to compress the biasing elements and hold the first and second jaws together;

a hole in the first jaw configured to receive the shaft; and

a locator pin that is received within the at least one groove of the shaft to releasably couple the second member and the pin clamp.

The Examiner asserts that claim 25 is obvious in view of *Faccioli* combined with *Wagenknecht*. However, for reasons similar to those described above with respect to claim 18, the cited references, either alone or in combination, fail to teach or suggest a hole in the first jaw of the pin clamp that is “configured to receive the shaft” [that extends transversely from an end portion of the second member and has at least one groove extending around at least a portion of a circumference of the shaft] or “a locator pin that is received within the at least one groove of the shaft to releasably couple the second member and the pin clamp.”

Additionally, the Action cites *Wagenknecht* as teaching the biasing elements recited in claim 25. However, the springs described in *Wagenknecht* are used “to spread the grips 120 and 130 one from another, in order to facilitate introduction of the pins 5.” *See* col. 6, ll. 40-42. In contrast, the biasing elements in amended claim 25 are “adapted to bias the first and second jaws toward each other.” *Wagenknecht* fails to teach this limitation of claim 25.

For the above reasons, the Examiner should withdraw the rejection of claim 25 as obvious in view of the combination of *Faccioli* and *Wagenknecht*, and claim 25 should be allowed. Inasmuch as claims 28 and 29 depend from and thereby include the limitations of claim 25, claims 28 and 29 should also be allowed for at least such dependencies.

Claims 30-33

Amended claim 30 recites:

A method of treating a skeletal condition or injury using an external fixation apparatus, the method comprising:

- (a) fixing a first member to a first side of a fracture with upper bone pins;
- (b) fixing a pin clamp to a second side of the fracture with lower bone pins; and

(c) coupling the pin clamp to the first member through the use of a pivot arm having first and second end portions, the first member being coupled to the first end portion through a lockable ball joint and the pin clamp being coupled to the second end portion through a second lockable joint;

(d) adjusting the first and second end portions relative to each other and transversely relative to a longitudinal axis of the pivot arm to precisely reduce the fracture.

For reasons similar to those described above with respect to apparatus claim 1, *Faccioli* does not teach or suggest each and every element of amended method claim 30. More specifically, *Faccioli* does not teach or suggest adjusting the first and second end portions of a pivot arm relative to each other and transversely relative a longitudinal axis of the pivot arm.

For these reasons, the Examiner should withdraw the rejection of claim 30 as anticipated by *Faccioli*, and claim 30 should be allowed. Inasmuch as claims 31-33 depend from and thereby include the limitations of claim 30, claims 31-33 should also be allowed for at least such dependencies.

Conclusion

The foregoing, along with an RCE, is submitted as a full and complete response to the Action mailed August 7, 2006. Assignee submits that claims 1-5, 16-21, 23-25, 28-34, 36, and 41 are in condition for allowance, and notice of allowance is respectfully requested. The preceding arguments in favor of patentability are advanced without prejudice to other bases of patentability. If the Examiner believes there are any issues that can be resolved via a telephone conference, or there are any informalities that can be corrected by an Examiner's amendment, please call Geoffrey Gavin at (404) 815-6046.

AMENDMENT AND RESPONSE TO FINAL OFFICE ACTION
U.S. Serial No. 10/607,010

Other than the fee for the RCE being filed concurrently herewith, the undersigned attorney believes no fees are due; however, the Commissioner is authorized to debit deposit account no. 11-0855 to the extent necessary if other fees are due.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'GK Gavin', written over a horizontal line.

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